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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,923	11/25/2003	Janet Codd	102458-40933 (Nascime 2)	8326

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,923	CODD ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group II, consisting of claims 12-21, drawn to a pharmaceutical oral unit dosage form comprising two separate compartments each containing a composition comprised a pharmaceutical active ingredient of the compound of the formula I, classified in class 514, subclass 247 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-11 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Media Release (November 4, 2002) in view of Hirsh et al. (US 2003/0035839 A1).

Media Release announces positive phase II results for ocinaplon as a novel anti-anxiety product in its therapeutic use for generalized anxiety disorders. (title). Media Release teaches that ocinaplon is a non-benzodiazepine that exhibits anxiolytic-like effects in animal studies as a similar pharmacological profile to anxiolytic benzodiazepines. Media Release teaches controlled-release ocinaplon administered twice or three times a day is effective in the treatment of patients with generalized anxiety disorders. Media Release teaches ocinaplon was administered orally 60mg three times a day or 120mg twice a day for 14 days. (Content).

Media Release does not teach the two separate compartments each containing ocinaplon with specific amounts with rapid release in first compartment and sustained

release in second compartment with hydrophilic polymeric matrix (hydroxypropyl methyl cellulose) in a unit dose, carriers such as lactose and a particle size.

Hirsh et al. teach new pharmaceutical composition in unit dosage form comprising anxiolytic in two different portions comprising immediate (outer layer) as well as sustained release (core). (abstract, [0012], [0014], [0028], [0038]-[0042]). Hirsh et al. teach that the inner core of the composition can be formulated as a delayed release coating with hydroxypropyl methylcellulose. ([0060]. Hirsh et al. teach that the core of the composition can be formulated with inert carrier such as lactose. ([0031]). Hirsh et al. teach that the active ingredient of the composition may be the same pharmaceutically active ingredient. ([0014]). Hirsh et al. teach that the composition provides immediate as well as sustained and prolonged therapeutic benefit and improves compliance. ([0016]-[0012]).

It would have been obvious to one of ordinary skill in the art to modify the controlled-release ocinaplon of Media Release to the composition in unit dosage form comprising two portions as taught by Hirsh et al. One would have been motivated to make such a modification in order to achieve the advantage of two portion comprising immediate as well as sustained release to improve prolonged therapeutic benefit and improve the compliance as taught by Hirsh et al. It would have been obvious to one of ordinary skill in the art to employ hydroxypropyl methyl cellulose in delayed release coating since Hirsch et al teaches that the hydroxypropyl methyl cellulose is useful in delayed release portion as a coating. One would have been motivated to make such a modification with a reasonable expectation of successfully coating delayed portion with

hydroxypropyl methyl cellulose as taught by Hirsch et al. The amounts of active agent (ocinaplon) to be used in each portion, the pharmaceutical carriers (e.g. lactose), and the particle size are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and each portion can be formulated with same active agent contained therein and the utilization of lactose as a carrier is well taught by Hirsch et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
May 16, 2005